

Title: Passive Immunization Against Clostridium Difficile
Disease
Applicant(s): William D. Thomas, Jr. et al.
Filing Date: December 16, 2003
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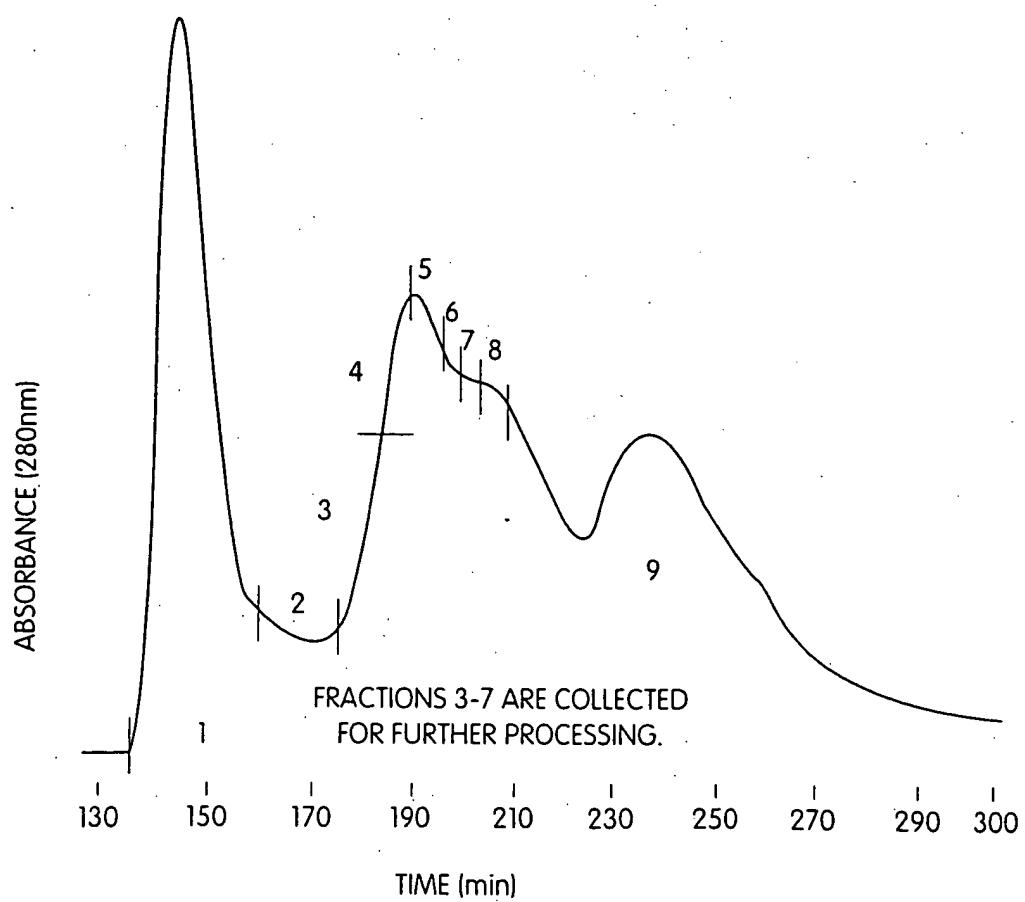


Fig. 1

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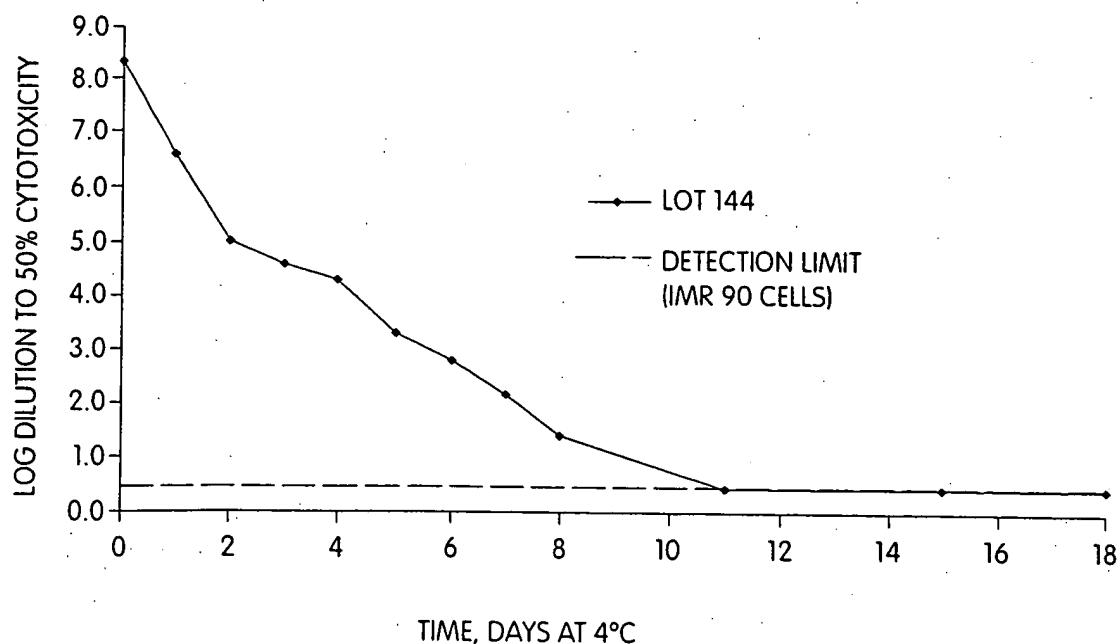
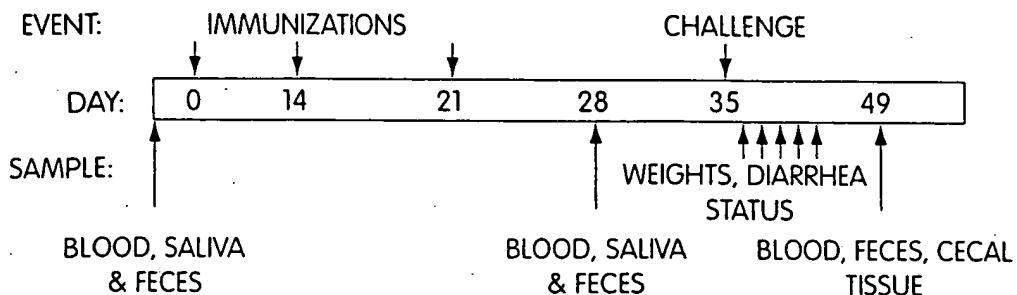


Fig. 2

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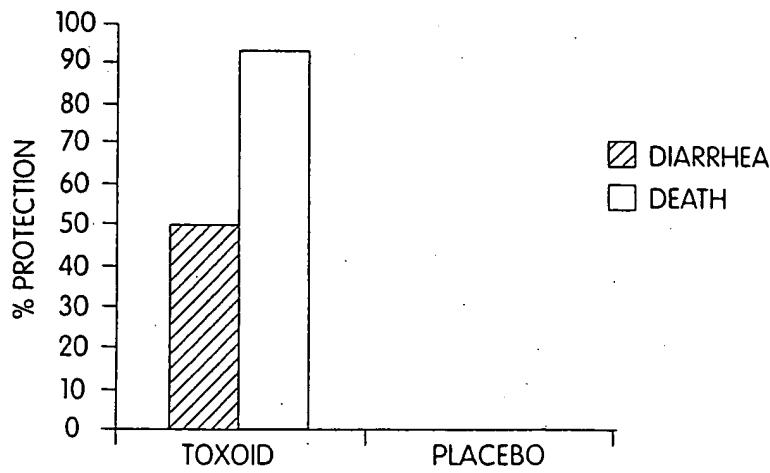
EXPERIMENTAL DESIGN:



INTRAMUSCULAR (IM) IMMUNIZATION OF HAMSTERS USING TOXOID VACCINE.

ANTIGEN	DOSE(µg)	ROUTE	ADJUVANT	NO. ANIMALS
TOXOID	100	IM	NONE	15
PLACEBO	NONE	IM	ALUM	10

Fig. 3



TREATMENT GROUPS

Fig. 4

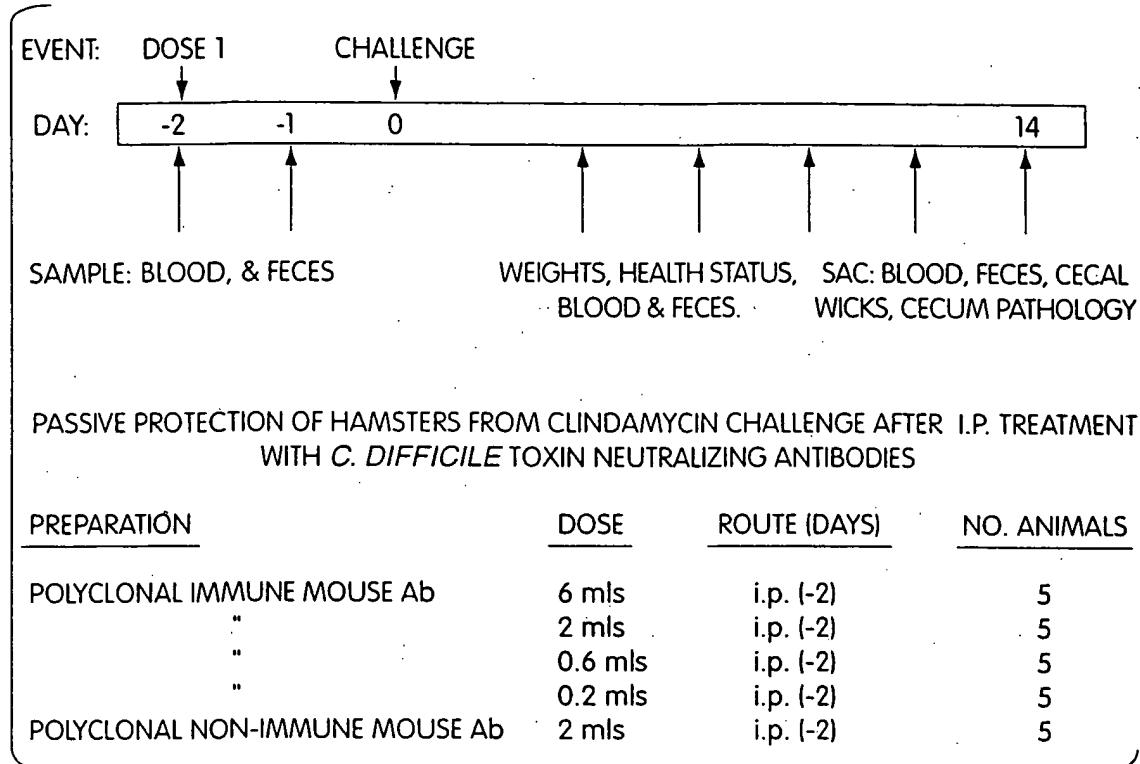


Fig. 5

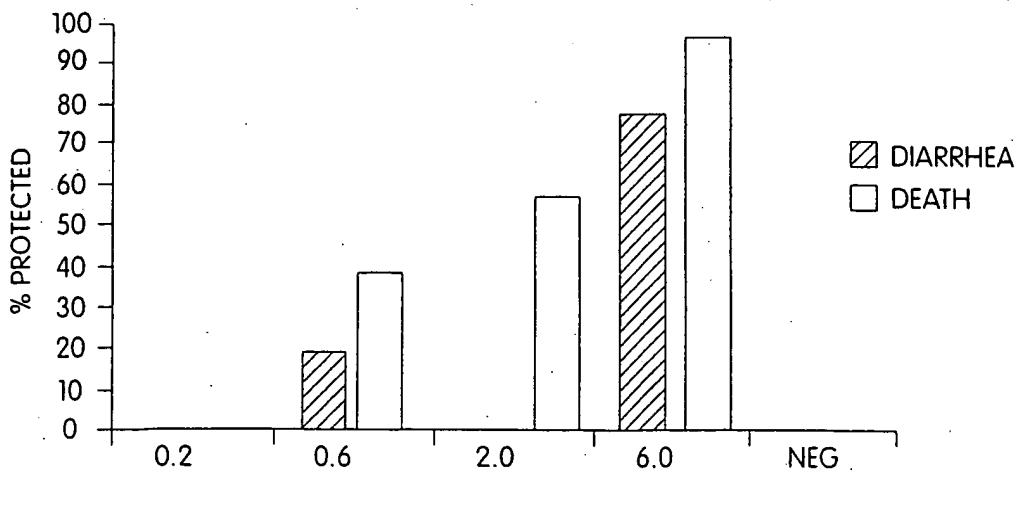
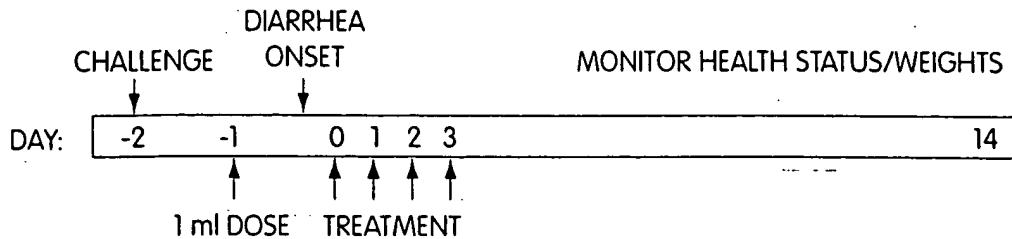


Fig. 6

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EXPERIMENTAL DESIGN:



ANTIBODY TREATMENT OF HAMSTERS FOLLOWING CLINDAMYCIN CHALLENGE (I.P.
ADMINISTRATION OF *C. DIFFICILE* TOXIN NEUTRALIZING ANTISERA
AFTER ONSET OF DIARRHEA).

PREPARATION	DOSE	ROUTE (DAYS)	NO. ANIMALS
POLYCLONAL IMMUNE MOUSE Ab	2 mls	i.p. (0,1,2,3)	5
POLYCLONAL NON-IMMUNE MOUSE Ab	2 mls	i.p. (0,1,2,3)	5
CHALLENGE ONLY			3

Fig. 7

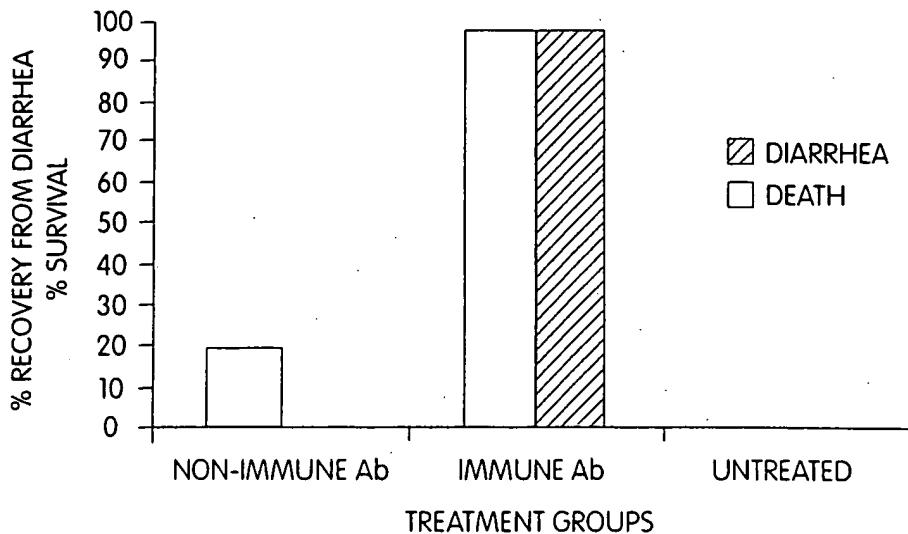
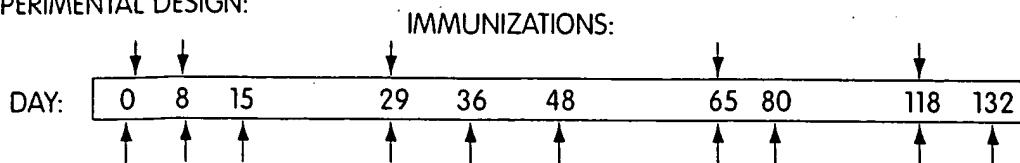


Fig. 8

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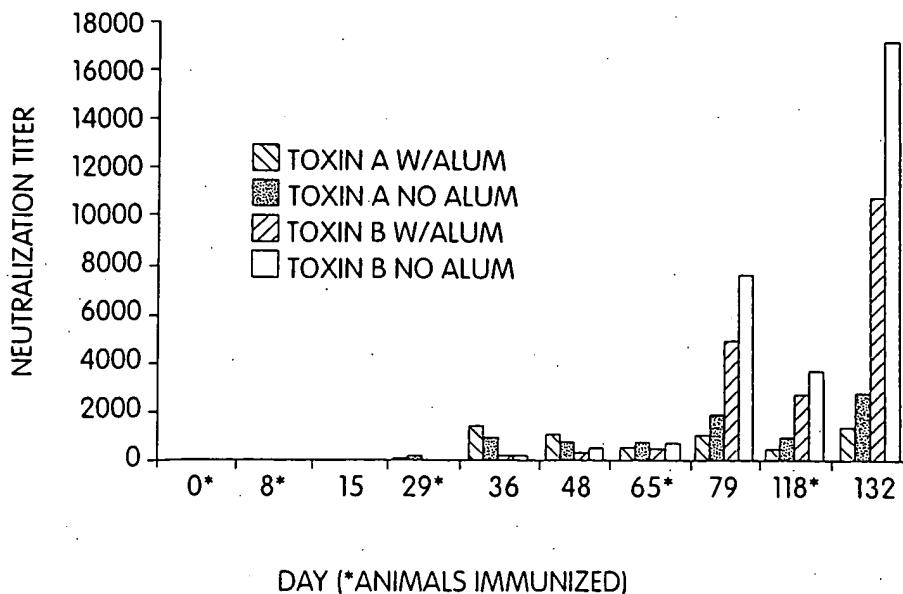
EXPERIMENTAL DESIGN:



BLOOD SAMPLE: NEUTRALIZATION, ELISA, HEMATOLOGY
AND CLINICAL CHEMISTRY

<u>ANTIGEN</u>	<u>DOSE(μg)</u>	<u>ROUTE</u>	<u>ADJUVANT</u>	<u>NO. ANIMALS</u>
TOXOID	110	IM	ALUM	3
TOXOID	110	IM	NONE	3
PLACEBO	NONE	IM	NONE	3

Fig. 9



* NO RESPONSE WAS DETECTED IN PLACEBO TREATED ANIMALS.

Fig. 10

Fig. 11

